Package leaflet: Information for the user

Gliolan 30 mg/ml powder for oral solution
5-aminolevulinic acid hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Gliolan is and what it is used for

Gliolan is used for the visualisation of certain brain tumours (called malignant glioma) during tumour surgery.

Gliolan contains a substance called aminolevulinic acid (5-ALA). 5-ALA accumulates preferably in tumour cells where it is transformed into another similar substance. If the tumour is then exposed to blue light, this new substance emits a red-violet light which helps to better see what is normal tissue and what is tumour tissue. This helps the surgeon to remove the tumour while sparing healthy tissue.

2. What you need to know before you take Gliolan

Do not take Gliolan
- if you are allergic to 5-ALA or porphyrins.
- in case of known or suspected acute or chronic types of porphyria (i.e. inherited or acquired disorders of certain enzymes in the synthesis pathway of red blood pigment).
- in case of known or suspected pregnancy.

Warnings and precautions
Talk to your doctor or pharmacist before taking Gliolan.
- For 24 hours after administration of this medicine, **protect your eyes and skin from strong light** (for example direct sunlight or brightly focused indoor light).
- If you have a **heart disease** or had heart disease in the past, you should tell your doctor. In this case, this medicine should be used with caution because your blood pressure may be decreased.

Renal or hepatic impairment
No trials have been performed in patients with poor liver or kidney function. Therefore, this medicine should be used with caution in such patients.

Elderly
There are no special instructions for use in elderly patients with normal organ function.

Children and adolescents (< 18 years)
There is no experience with Gliolan in children and adolescents. Therefore this medicine is not recommended in this age group.

Other medicines and Gliolan
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, particularly medicines that may cause skin problems when the skin comes under strong light (for example some types of medicines called antibiotics), but also medicines obtained without prescription (for example hypericin or Saint John's wort extracts).

One case of severe sunburn lasting for 5 days has been reported in a patient after having taken this medicine and a hypericin extract. You should not take any such products up to 2 weeks after you have taken Gliolan.

Within 24 hours after having taken Gliolan, avoid any other medicines that may harm the liver.

Gliolan with food and drink
This medicine is generally used once only, namely 2-4 hours before anaesthesia for surgery for certain brain tumours called glioma. You should not drink or eat for at least 6 hours before anaesthesia.

Pregnancy and breast-feeding
Pregnancy
It is not known whether Gliolan will harm an unborn baby. Do not use this medicine if you are pregnant.

Breast-feeding
It is not known whether this medicine enters breast milk. Breast-feeding mothers should not breast-feed for 24 hours after treatment with this medicine.

Driving and using machines
This medicine itself has no influence on the ability to drive and use machines.

3. How to take Gliolan

This medicine is a powder that must be first mixed with drinking water before use. This is always done by a pharmacist or a nurse and not by yourself. The usual dose is 20 mg 5-ALA HCl per kilogram body weight. The pharmacist or nurse will calculate the exact dose you need and the amount of the solution (in ml) you have to drink. You have to drink the prepared solution 2-4 hours before anaesthesia.

If the surgery is postponed by more than 12 hours, surgery should be re-scheduled for the next day or later. Another dose of this medicine can be taken 2 – 4 hours before anaesthesia.

If you take more Gliolan than you should
If you have taken more Gliolan than you should, your doctor will decide on any necessary measures to avoid any problems, including sufficient protection from strong light (for example direct sunlight).

If you forget to take Gliolan
This medicine is given once only at the day of surgery, 2 – 4 hours before start of anaesthesia. If you have forgotten to take this medicine during this time period, it is not advisable to take it just before start of anaesthesia. In this case, anaesthesia and surgery must be postponed for at least 2 hours, if possible.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Most serious side effects include mild alterations of blood cell counts (red and white cells, platelets), disorders that affect the nervous system (neurological disorders) like partial paralysis of one side of the body (hemiparesis) and blood clots that may obstruct blood vessels (thromboembolism). Further frequently observed side effects are being sick (vomiting), feeling sick (nausea) and slight increase of some enzymes (transaminases, γ-GT, amylase) or bilirubin (a bile pigment produced in the liver by breakdown of red blood pigment) in the blood.

Tell your doctor immediately if you experience any complaints.

Side effects are divided into the following two categories:
- immediate side effects after having taken Gliolan and before anaesthesia
- combined side effects of Gliolan, anaesthesia, and tumour resection.

After having taken Gliolan and before start of anaesthesia, the following side effects may occur:

Uncommon side effects (may affect up to 1 in 100 people):
Feeling sick (nausea), decrease of blood pressure (hypotension), skin reactions (for example rash, looking like sunburn).

In combination with anaesthesia and tumour resection further side effects may occur:

Very common side effects (may affect more than 1 in 10 people):
Mild alterations of blood cell counts (red and white cells, platelets), and slight increase of some enzymes (transaminases, γ-GT, amylase) or bilirubin (a bile pigment produced in the liver by breakdown of red blood pigment) in the blood. These changes peak between 7 and 14 days after surgery. The changes will completely resolve within a few weeks. Usually you will not experience any symptoms when these changes occur.

Common side effects (may affect up to 1 in 10 people):
Feeling sick (nausea), being sick (vomiting), disorders that affect the nervous system (neurological disorders) like partial paralysis of one side of the body (hemiparesis), total or partial loss of ability to use or understand language (aphasia), seizures (convulsions) and blindness for half the field of vision in one or both eyes (hemianopsia), and blood clots that may obstruct blood vessels (thromboembolism).

Uncommon side effects (may affect up to 1 in 100 people):
Decrease of blood pressure (hypotension), brain swelling (brain oedema).

Very rare side effects (may affect up to 1 in 10 000 people) or not known (frequency cannot be estimated from the available data):
Decrease of your sense of touch (hypaesthesia), and loose or watery stools (diarrhoea).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

United Kingdom (Northern Ireland)
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Gliolan

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Keep the bottle in the outer carton in order to protect from light.

The reconstituted solution is physically-chemically stable for 24 hours at 25 °C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Gliolan contains
The active substance is 5-aminolevulinic acid hydrochloride (5-ALA HCl). One bottle contains 1.17 g of 5-aminolevulinic acid (5-ALA), corresponding to 1.5 g 5-ALA HCl.
One ml of reconstituted solution contains 23.4 mg of 5-ALA, corresponding to 30 mg 5-ALA HCl.

What Gliolan looks like and contents of the pack
This medicine is a powder for oral solution. The powder is a white to off-white cake. The reconstituted solution is a clear and colourless to slightly yellowish fluid.
Gliolan is provided in a glass bottle and presented in packs of 1, 2 and 10 bottles. Not all pack sizes may be marketed.

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Manufacturer
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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.